

## **CALCIUM ACETATE - calcium acetate capsule**

Roxane Laboratories, Inc

### **RX ONLY**

### **DESCRIPTION**

Each white opaque/blue opaque gelcap contains 667 mg of calcium acetate, (anhydrous;  $\text{Ca}(\text{CH}_3\text{COO})_2$ ; MW=158.17 grams) equal to 169 mg (8.45 mEq) calcium. Each capsule also contains FD&C blue #1, FD&C red #3, gelatin, magnesium stearate, polyethylene glycol 8000, and titanium dioxide. In addition to the ingredients listed above, each capsule contains Opacode (Black) monogramming ink. Opacode (Black) contains ethanol, FD&C blue #2, FD&C red #40, FD&C yellow #6, iron oxide black, Nbutyl alcohol, propylene glycol, and shellac. Calcium Acetate Capsules are administered orally for the control of hyperphosphatemia in end stage renal failure.

### **CLINICAL PHARMACOLOGY**

Patients with advanced renal insufficiency (creatinine clearance less than 30 mL/min) exhibit phosphate retention and some degree of hyperphosphatemia. The retention of phosphate plays a pivotal role in causing secondary hyperparathyroidism associated with osteodystrophy, and soft-tissue calcification. The mechanism by which phosphate retention leads to hyperparathyroidism is not clearly delineated. Therapeutic efforts directed toward the control of hyperphosphatemia include reduction in the dietary intake of phosphate, inhibition of absorption of phosphate in the intestine with phosphate binders, and removal of phosphate from the body by more efficient methods of dialysis. The rate of removal of phosphate by dietary manipulation or by dialysis is insufficient. Dialysis patients absorb 40% to 80% of dietary phosphorus. Therefore, the fraction of dietary phosphate absorbed from the diet needs to be reduced by using phosphate binders in most renal failure patients on maintenance dialysis. Calcium acetate when taken with meals, combines with dietary phosphate to form insoluble calcium phosphate which is excreted in the feces. Maintenance of serum phosphorus below 6.0 mg/dl is generally considered as a clinically acceptable outcome of treatment with phosphate binders. Calcium acetate is highly soluble at neutral pH, making the calcium readily available for binding to phosphate in the proximal small intestine. Orally administered calcium acetate from pharmaceutical dosage forms has been demonstrated to be systemically absorbed up to approximately 40% under fasting conditions and up to approximately 30% under nonfasting conditions. This range represents data from both healthy subjects and renal dialysis patients under various conditions.

### **INDICATIONS AND USAGE**

Calcium Acetate Capsules are indicated for the control of hyperphosphatemia in end stage renal failure and do not promote aluminum absorption.

### **CONTRAINDICATIONS**

Patients with hypercalcemia.

### **WARNINGS**

Patients with end stage renal failure may develop hypercalcemia when given calcium with meals. No other calcium supplements should be given concurrently with calcium acetate capsules. Progressive hypercalcemia due to overdose of calcium acetate may be severe as to require emergency measures. Chronic hypercalcemia may lead to vascular calcification, and other soft-tissue calcification. The serum calcium level should be monitored twice weekly during the early dose adjustment period. **These serum calcium times phosphate (CaXP) product should not be allowed to exceed 66.** Radiographic evaluation of suspect anatomical region may be helpful in early detection of soft-tissue calcification.

### **PRECAUTIONS**

#### **General**

Excessive dosage of calcium acetate induces hypercalcemia; therefore, early in the treatment during dosage adjustment serum calcium should be determined twice weekly. Should hypercalcemia develop, the dosage should be reduced or the treatment discontinued immediately depending on the severity of hypercalcemia. Calcium acetate should not be given to patients on digitalis, because hypercalcemia may precipitate cardiac arrhythmias. Calcium acetate therapy should always be started at low dose and should not be increased without careful monitoring of serum calcium. An estimate of daily calcium intake should be made initially and the intake adjusted as needed. Serum phosphorus should also be determined periodically.

#### **Information for patients**

The patients should be informed about compliance with dosage instructions, adherence to instructions about diet and avoidance of the use of nonprescription antacids. Patients should be informed about the symptoms of hypercalcemia (see **ADVERSE REACTIONS**).

#### **Drug interactions**

Calcium acetate may decrease the bioavailability of tetracyclines.

**Carcinogenesis, mutagenesis, impairment of fertility**

Long-term animal studies have not been performed to evaluate the carcinogenic potential, mutagenicity, or effect on fertility of calcium acetate.

**Pregnancy**

Teratogenic effects: Category C:

Animal reproduction studies have not been conducted with calcium acetate. It is not known whether calcium acetate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Calcium acetate should be given to a pregnant woman only if clearly needed.

**Pediatric use**

Safety and effectiveness in pediatric patients have not been established.

**Geriatric use**

Of the total number of subjects in clinical studies of calcium acetate (N=91), 25 percent were 65 and over, while 7 percent were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

**ADVERSE REACTIONS**

In clinical studies, patients have occasionally experienced nausea during calcium acetate therapy. Hypercalcemia may occur during treatment with calcium acetate. Mild hypercalcemia ( $\text{Ca} > 10.5 \text{ mg/dl}$ ) may be asymptomatic or manifest itself as constipation, anorexia, nausea and vomiting. More severe hypercalcemia ( $\text{Ca} > 12 \text{ mg/dl}$ ) is associated with confusion, delirium, stupor and coma. Mild hypercalcemia is easily controlled by reducing the calcium acetate dose or temporarily discontinuing therapy. Severe hypercalcemia can be treated by acute hemodialysis and discontinuing calcium acetate therapy. Decreasing dialysate calcium concentration could reduce the incidence and severity of calcium acetate induced hypercalcemia. The long-term effect of calcium acetate on the progression of vascular or soft-tissue calcification has not been determined. Isolated cases of pruritus have been reported which may represent allergic reactions.

**Overdosage**

Administration of calcium acetate in excess of the appropriate daily dosage can cause severe hypercalcemia (see **ADVERSE REACTIONS**).

**DOSAGE AND ADMINISTRATION**

The recommended initial dose of calcium acetate capsules for the adult dialysis patient is 2 capsules with each meal. The dosage may be increased gradually to bring the serum phosphate value below 6 mg/dl, as long as hypercalcemia does not develop. Most patients require 3 to 4 capsules with each meal.

**HOW SUPPLIED**

Calcium Acetate Capsules are supplied as white opaque/blue opaque capsules imprinted with "54 215" on the cap and body. 0054-0088-26 667 mg, white opaque/ blue opaque capsule, bottle of 200

**STORAGE**

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

**10003705/01**

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**PACKAGE LABEL - CALCIUM ACETATE CAPSULES, 667 MG**

0054-0088-26 - 200 Capsules

Rx Only

Roxane Laboratories, Inc.

NDC 0054-0088-26 200 Capsules

# CALCIUM ACETATE Capsules

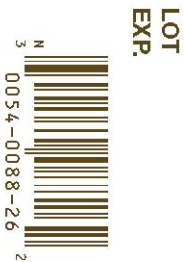
**667 mg**

Each capsule contains 667 mg  
calcium acetate equivalent to  
169 mg calcium.

DIRECTIONS: SWALLOW  
CAPSULES: DO NOT CHEW.

Take as directed by your physician.

**R<sub>x</sub> only**



**KEEP THIS AND ALL DRUGS OUT  
OF THE REACH OF CHILDREN.**

Store at 20° to 25°C (68° to 77°F).  
[See USP Controlled Room  
Temperature.]



Boehringer Ingelheim

Roxane Laboratories

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